Ionising Radiation (Medical Exposure) Regulations 2000

Guidance pertaining to image interpretation/initial image commenting/ image reporting



The Society & College of Radiographers

The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R) came into force on 13 May 2000, in concordance with the European Directive 97/43/Euratom (The Medical Exposures Directive, 1997). The Regulations were amended in 2006 and 2011 (not including Northern Ireland, presently).

IR(ME)R identifies four duty holders, each of whom has clearly identified responsibilities under the Regulations: the Employer, Referrer, Practitioner and Operator. The Employer has a number of legal obligations including establishing a framework of written procedures and protocols under which the duty holders work, as well as entitling the duty holders for the tasks they may perform under IR(ME)R. The Employer is normally considered to be the Chief Executive Officer, however the task of leading on IR(ME)R matters may have been delegated to an alternative individual who should be of sufficient seniority (eg, at board level). It is imperative that all duty holders know who the IR(ME)R Employer is for their area.

Clinical Evaluation

Regulation 7(8) of IR(ME)R requires the Employer to ensure that a clinical evaluation of the outcome of each medical exposure is recorded and to set out in procedure, how and by whom this is to be done. The record should include factors relevant to patient dose, where appropriate. It is important to note that if no evaluation of an exposure is carried out, then that exposure cannot be justified and therefore should not be undertaken. It is considered that clinical evaluation is carried out by an "Operator" under IR(ME)R. This person must be entitled accordingly by the Employer.

The evaluation of an exposure is normally recorded via the imaging report and may be an initial report or final report. The evaluation may be carried out by radiologists, radiographers, non-radiological clinicians or healthcare professionals; however they must be entitled as an Operator for that purpose. Where the report is recorded will depend on local circumstances but may be, for example, within the patients' notes or on PACS. The report should be produced in a timely fashion to allow further appropriate patient management. The process of making and recording of a clinical evaluation for each exposure should be clearly described in written procedure.

Entitlement

Entitlement by the Employer means that permission has been given to act, in compliance with the Regulations, according to the specific responsibilities of a duty holder role (ie, "Operator"). There must be a documented entitlement process, within the Employers' procedures, that details the mechanism through which an individual becomes entitled.

As part of the entitlement, the Employer should specify the scope of practice and the tasks which an individual can carry out as an entitled "Operator". It is important to note that the Employer must be able to demonstrate that the Operator is adequately trained to undertake those tasks (Regulation 4(4)(a),(b)).

An example of the process of entitlement could involve the distribution of a signed letter detailing the specifics of that entitlement – in terms of image interpretation and reporting, this could include a table of radiology procedures that the individual is deemed competent and entitled to evaluate (report). Entitlement could be considered to provide a safety check for both the Employer and the individual in that the Employer is confident in the ability of the staff. In terms of IR(ME)R, no staff member may be asked to carry out a task for which they have not been trained nor entitled to do.

Operator

The definition of the IR(ME)R "Operator" is 'any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects'.

Operators are legal duty holders who have been entitled by the Employer to carry out practical aspects of a medical exposure. These include the clinical evaluation of an exposure (ie, the interpretation and reporting of the image).

Training

Individuals entitled to act as an "Operator" must have undergone training in those subjects in Sections A and B of Schedule 2 of IR(ME)R 2000 which are relevant to their functions. The Employer must be satisfied that the individual has undergone adequate training and is competent to carry out the tasks at the point of entitlement. Similarly there is an obligation on the Operators to not carry out any practical aspect unless they have been adequately trained (Regulation 11(1)).

It is the Employer's responsibility to maintain documented and up-to-date evidence of "adequate training" for all entitled IR(ME)R duty holders. (Regulation 11(4)). Training records should reflect relevant education and training, including continuous development and local department specific training as well as that achieved through additional external qualifications and courses

IR(ME)R Procedure

To avoid lengthy descriptions about different staff groups at different levels of training / competency having to be included in procedure, it may be helpful to simplify in writing the IR(ME)R procedure relating to clinical evaluation by including a statement such as the following:

Image interpretation and reporting can only be carried out by an adequately trained, competent operator who has been entitled to do so by the Employer. A trainee can undertake image interpretation and reporting under the supervision of a competent entitled operator who is responsible for the task being completed correctly.

A matrix of image interpretation and reporting tasks and entitled operators is held and maintained by the Clinical Director of the imaging department.

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